ORIGINAL RESEARCH

Trends in Utilization, Spending, and Prices of Smoking-Cessation Medications in Medicaid Programs: 25 Years Empirical Data Analysis, 1991-2015

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BACKGROUND: Smoking remains the single largest preventable cause of death and disease. Smoking-cessation medications provide patients a multitude of benefits and can prevent certain diseases, including some cancers. Because of the limited amount of studies on smoking-cessation medications, we wanted to find general trends about the use of these medications.

OBJECTIVE: To examine trends in the utilization, pharmacy reimbursement, and prices of smoking-cessation medications and nicotine replacement therapy in the US Medicaid-covered population.

METHODS: Using national summary files for outpatient drug utilization and expenditure, we extracted data on smoking-cessation medications from the Centers for Medicare & Medicaid Services in the 25 years from January 1991 through June 2015. We conducted a retrospective drug utilization study to examine the annual (or quarterly) trends of the number of prescriptions, reimbursement expenditures, and the prices of smoking-cessation medications. The study drugs included varenicline (Chantix), bupropion (Zyban), and nicotine. We calculated per-prescription pharmacy reimbursement, which was used as a proxy for drug price, as the total quarterly expenditure for the drug, divided by the total number of prescriptions. All expenditures were inflated to 2015 US dollars using the medical services component of the Consumer Price Index.

RESULTS: The total number of prescriptions for smoking-cessation medications increased rapidly from 46,396 in 1991 to 942,562 in 2014, an increase of more than 1931%. During the same period, the total pharmacy reimbursement for smoking-cessation medications in Medicaid increased by 3562%, from approximately $2.8 million in 1991 to approximately $101 million in 2014. The use of the nonnicotine prescription drugs varenicline and bupropion also increased rapidly, with a high cost expenditure. The price per nonnicotine prescription drug increased over time, ranging from approximately $169 for bupropion to approximately $251 for varenicline in 2015.

CONCLUSIONS: The substantial increase in nonnicotine prescription drugs and nicotine replacement therapy between 2007 and 2015 may be attributed to smoking-cessation participants nationwide. Cost-containment policies might have inadvertently prevented Medicaid-covered smokers from obtaining appropriate pharmacotherapy.

Stakeholder Perspective, page 284

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KEY WORDS: drug utilization, Medicaid, nicotine replacement therapy, nonnicotine prescription, reimbursement, smoking, smoking-cessation medication

Smoking remains the single largest preventable cause of death and disease, and is responsible for 1 in 5 deaths in the United States each year.[1] In 2015, more than 1.1 billion people smoked tobacco worldwide, with a much higher prevalence among men than in women.[2] Nearly 171,000 of the approximate 589,400 cancer-related deaths in the United States result from tobacco smoking.[3] People who smoke are at an increased risk for various types of cancer.[4] Cigarette smoking is also a major risk factor for heart disease, cardiovascular disease, and other serious diseases.[5]

In addition, smoking imposes a huge economic burden on society. Smoking-related illness in the United States costs more than $300 billion annually, including nearly $170 billion in direct medical care costs for adults

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KEY POINTS

- Smoking is the largest preventable cause of disease and death in the United States, but the use of smoking-cessation aids can help smokers successfully quit.
- This retrospective study examined the quarterly trends of prescribing, utilization, pharmaceutical reimbursement, and smoking-cessation medication cost.
- The total number of prescriptions for smoking-cessation medications increased more than 1931% from 46,396 in 1991 to 942,562 in 2014.
- In the same period, the reimbursement for smoking-cessation medications increased 3562%, from approximately $2.8 million in 1991 to approximately $101 million in 2014.
- The price per nonnicotine prescription increased over time, averaging approximately $169 for Zyban to approximately $251 for Chantix in 2015.
- The surge in nonnicotine prescription and nicotine replacement therapies from 2007 to 2015 might be attributed to smoking-cessation participants.
- Cost-containment policies might have unintentionally barred Medicaid-covered smokers from receiving appropriate pharmacotherapy.

and $156 billion in lost productivity.[6,7] Smoking-cessation agents can bring a multitude of benefits by lowering a smoker's risk for various cancers, heart disease, and stroke, as well as helping to prevent heart disease and lung cancer in people who are exposed to secondhand smoke.[8] A study by Nash and colleagues shows that former smokers had a substantially lower mortality risk after age 70 years compared with current smokers, even among patients who quit tobacco use in their 60s. Therefore, all smokers should be encouraged to stop smoking, regardless of their age.[9]

The US Food and Drug Administration (FDA) has approved a variety of smoking-cessation aids, including prescription drugs and over-the-counter (OTC) products, such as skin patches, lozenges, and gum. Varenicline (Chantix) and bupropion (Zyban) are smoking-cessation medications that do not contain nicotine. Varenicline is a partial agonist of $\alpha 4\beta 2$ nicotinic acetylcholine receptors that acts in the brain at the sites affected by nicotine. Varenicline provides some nicotinelike effects to lessen the symptoms of withdrawal, and it prevents the effects of nicotine if cigarette users start smoking again after they stop smoking.[8] Bupropion is an antidepressant that also helps patients abstain from smoking; however, the precise means by which it accomplishes this is unknown.[10]

Nicotine replacement agents are one type of smoking-cessation aid. Designed to wean the body off of cigarettes, these nicotine replacements supply smokers with controlled amounts of nicotine, while sparing them from the other chemicals found in tobacco products. Nicotine replacement agents include prescription medicines and OTC products, including nicotine skin patches (eg, Habitrol, Nicoderm), lozenges (eg, Commit), and gum (eg, Nicorette). A prescription-only nicotine replacement medication is Nicotrol, which is available as a nasal spray and as an oral inhaler.[8]

Some of the most often observed adverse effects associated with the use of varenicline and bupropion include nausea, vomiting, and trouble sleeping.[11-15] In addition to warnings about the risks for serious psychiatric problems, the prescribing information for bupropion cites other adverse effects and risks related to this medication, including seizures, hypertension, and allergic reactions.[13] In July 2009, the FDA required the product information for varenicline and bupropion to carry new safety information for patients in a boxed warning on their labeling that cites serious neuropsychiatric effects for patients.[14,15] In 2016, the FDA determined that the risk for serious neuropsychiatric effects with varenicline and bupropion is lower than previously suspected based on an FDA review of a large clinical trial; thus, the boxed warnings for these 2 drugs have been removed.[16] Moreover, this review of the clinical trial results confirmed that varenicline, bupropion, and nicotine replacement medications were all more effective that previously thought in helping people quit smoking.[16]

To our knowledge, no studies have examined the utilization, expenditures, market-share competition, and patterns of smoking-cessation products among the Medicaid population.[17] To fill this gap, the objective of this study was to assess trends in utilization, reimbursement, and the average per-prescription cost of smoking-cessation products and nicotine replacement therapy for the US Medicaid population in the 25 years from 1991 through 2015.

Methods

We conducted a descriptive, retrospective data analysis for the period between the first quarter of 1991 and the second quarter of 2015 using the publicly available National Summary Files from the Medicaid State Drug Utilization Data database maintained by the Centers for Medicare & Medicaid Services (CMS). The database includes Medicaid beneficiaries from 49 states (ie, all US states except Arizona) and the District of Columbia, and is restricted to pharmaceuticals prescribed on an outpa-

tient basis. The CMS data were collected for individual National Drug Code (NDC) drug forms. The National Summary Files were compiled by aggregating data across state databases.

The database was subject to coding errors in 2006 (all 4 quarters) and in quarter 3 of 2007. During those 5 quarters, the number of prescriptions and reimbursements for some individual drugs, including smoking-cessation medications, were incorrectly reported. Therefore, we estimated those values by averaging the previous and subsequent quarters. In this way, we created the reimbursement and utilization estimates to have better face validity. The general results of this study were not affected by this small amount of "data cleaning."

Each data record in the database included the NDC, drug name (brand or generic), year and quarter of Medicaid expenditure, number of prescriptions, number of units (eg, individual capsules or tablets), and the total pharmacy reimbursement amount, including the costs of the medication and its dispensing fee (ie, administrative fee). The first 5 digits of the NDC number identify the drug manufacturer, and the remaining digits identify the specific drug by strength, dose formulation, and packaging. We searched the database for all smoking-cessation medications by using the brand and generic names (**Table 1**).

Table 1 Prescription and OTC Smoking-Cessation Medications Included in the Study

Smoking-cessation medication type[a]	Generic name	Brand name	Dosage form	FDA approval date	Extended expiration date[b]
Nonnicotine products	Varenicline	Chantix	Oral	5/10/2006	5/20/2020
	Bupropion	Zyban	Oral	5/14/1997	Expired
		Wellbutrin	Oral	12/30/1985	Expired
		Forfivo XL	Extended-release oral	11/10/2011	6/25/2027
OTC nicotine replacement	Nicotine	Habitrol	Transdermal patch	11/27/1991	Expired
		Nicoderm	Transdermal patch	11/7/1991	12/15/2019
		Nicorette	Chewing gum	1/13/1984	Expired
		Commit	Oral lozenge	10/31/2002	Expired
Prescription-only nicotine replacement		Nicotrol	Nasal spray	3/22/1996	Expired
		Prostep	Transdermal patch	1/28/1992	Withdrawn

[a]All data are from www.accessdata.fda.gov/scripts/cder/daf/index.cfm.
[b]All data are from www.accessdata.fda.gov/scripts/cder/ob/index.cfm.
FDA indicates US Food and Drug Administration; OTC, over-the-counter.

For each of the medications in Table 1, the quarterly prescription count and pharmacy reimbursement amounts were calculated by summarizing the data across individual NDCs for individual drugs and then for each

Figure 1 Quarterly Utilization of Nonnicotine Medications for Patients with Medicaid Coverage, 1991 to Mid-2015

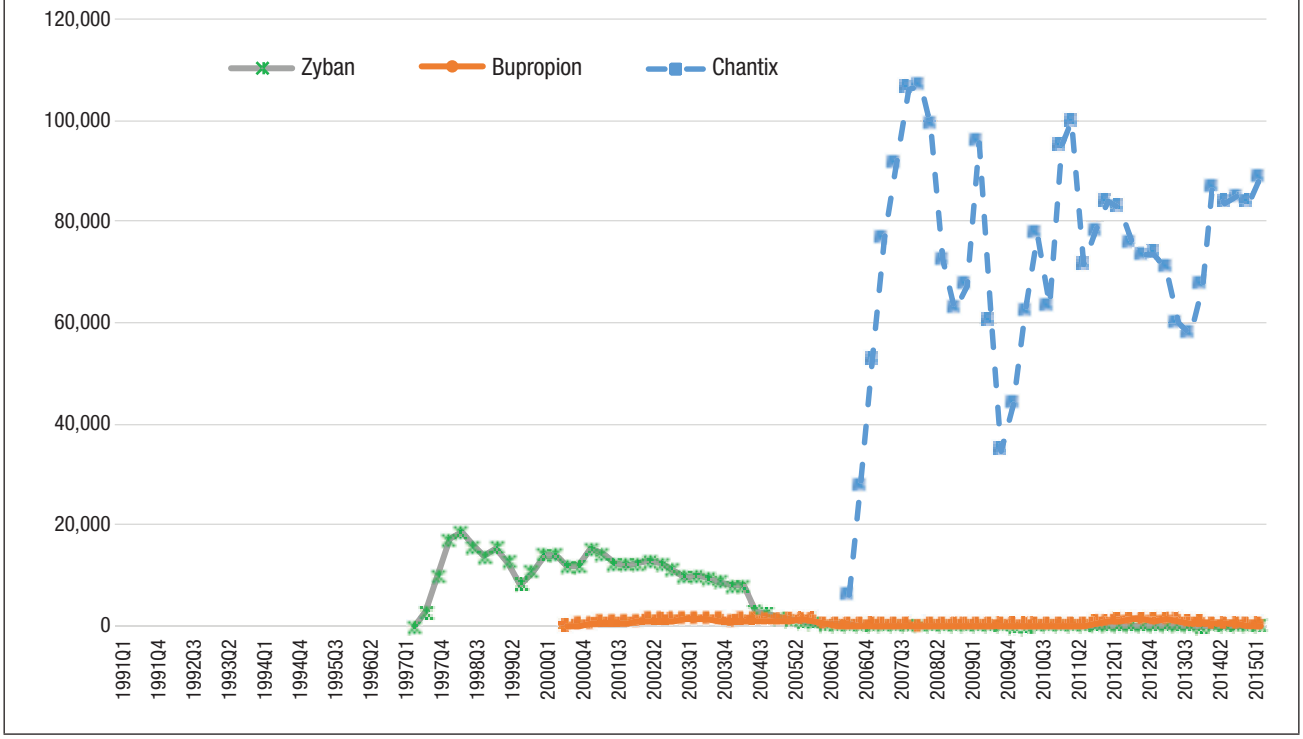


Table 2 Annual Medicaid Expenditures and Prescriptions for Smoking-Cessation Medications, 1991-2015

	Utilization and expenditure for total		Market share of nonnicotine products and nicotine replacement medications				Average price claim for smoking cessation		
Year	Prescriptions, N	Expenditure,[a] $	Nonnicotine medication prescriptions, %	Nicotine replacement products prescriptions, %	Nonnicotine medication spending,%	Nicotine replacement products spending, %	Nonnicotine medications,[a] $	Nicotine replacement products,[a] $	Combined,[a] $
1991	46,396	2,758,822	0.0	100.0	0.0	100.0		59.46	59.46
1992	212,440	22,343,916	0.0	100.0	0.0	100.0		105.18	105.18
1993	158,292	16,216,629	0.0	100.0	0.0	100.0		102.45	102.45
1994	120,036	12,575,937	0.0	100.0	0.0	100.0		104.77	104.77
1995	101,511	10,675,179	0.0	100.0	0.0	100.0		105.16	105.16
1996	91,148	10,130,444	0.0	100.0	0.0	100.0		111.14	111.14
1997	76,459	8,698,608	16.8	83.2	15.2	84.8	102.63	116.02	113.77
1998	137,376	14,556,134	47.6	52.4	47.3	52.7	105.48	106.39	105.96
1999	158,447	15,818,461	29.7	70.3	32.8	67.2	110.28	95.42	99.83
2000	210,830	21,668,737	24.7	75.3	27.5	72.5	114.45	98.94	102.78
2001	279,201	28,122,815	20.3	79.7	23.2	76.8	115.16	97.06	100.73
2002	364,542	37,246,437	14.5	85.5	17.2	82.8	121.03	98.97	102.17
2003	343,221	38,854,841	12.6	87.4	13.3	86.7	119.05	112.36	113.21
2004	315,409	35,240,744	8.3	91.7	8.8	91.2	119.66	111.02	111.73
2005	341,323	36,641,967	2.7	97.3	2.2	97.8	89.31	107.85	107.35
2006	262,713	26,946,527	13.7	86.3	15.0	85.0	112.27	101.03	102.57
2007	532,584	56,503,817	61.6	38.4	66.2	33.8	114.08	93.28	106.09
2008	546,792	59,814,467	62.5	37.5	67.9	32.1	118.87	93.61	109.39
2009	521,985	54,881,076	49.5	50.5	60.9	39.1	129.32	81.42	105.14
2010	522,095	52,669,511	47.3	52.7	64.2	35.8	136.80	68.61	100.88
2011	851,363	86,092,415	40.6	59.4	61.4	38.6	152.92	65.70	101.12
2012	877,596	87,370,367	36.5	63.5	62.3	37.7	170.03	59.10	99.56
2013	790,668	79,455,151	33.7	66.3	64.8	35.2	193.44	53.31	100.49
2014	942,562	101,036,840	34.4	65.6	69.5	30.5	216.61	49.78	107.19
2015[b]	552,297	62,613,536	31.3	68.7	69.3	30.7	250.95	50.70	113.37

[a]All monetary values were converted to 2015 US dollars using price indices.
[b]Data in 2015 are for quarters 1 and 2 only.

class of drugs, respectively. The data for all the generic versions of each drug were aggregated. Market shares for smoking-cessation medications were calculated based on the percentage of the number of prescriptions and the percentage of total Medicaid payments.

Bupropion is a treatment for depression and an aid for quitting smoking, of which Zyban is one brand name. Other brand names for bupropion are Wellbutrin and Forfivo XL, but these are approved for the treatment of major depressive disorder and not for smoking cessation. Thus, we excluded Wellbutrin and Forfivo XL in this study, although some physicians prescribe them off label to patients as smoking-cessation medications.

Quarterly per-prescription pharmacy reimbursements used as a proxy for drug price were computed for all brand-name and generic smoking-cessation medications. Pharmacy reimbursements include the drug ingredient cost and dispensing fee, but they exclude manufacturer rebates (ie, federally mandated rebates and state supplemental rebates have not been subtracted).

The price of medications was calculated as the total pharmacy reimbursements divided by the total number of prescriptions. All expenditures were inflated to 2015 US dollars using the Consumer Price Index medical services component. All data analyses were conducted using Statistical Analysis Software version 9.4 (SAS Institute Inc; Cary, NC). Excel 2013 (Microsoft; Redmond, WA) was used to further develop the data.

Results

The total number of Medicaid-reimbursed prescriptions for smoking-cessation medications increased rapidly from 46,396 in 1991 to 942,562 in 2014, a more than 1931% increase (**Table 2**). During the same period, the

total Medicaid reimbursement for these medications increased by 3562%, from approximately $2.8 million in 1991 to approximately $101.0 million in 2014.

Table 2 also shows utilization and payment market shares for the 2 medications. Nicotine replacement medications had 100% of the Medicaid market share for prescriptions from 1991 to 1996. Their share fell to 37.5% by 2008 and was back to 68.7% by 2015. Since nonnicotine smoking-cessation drugs came into the market in 1997, the expenditure of smoking-cessation medications has continually increased—from 15.2% in 1997 to 69.3% in 2015. Once Chantix became available on the market in 2006, the dollar market share for smoking-cessation drugs suddenly exceeded the dollar market share of nicotine replacement products and remained higher through 2015.

In the first half of 2015, Medicaid programs combined spent more than $62.6 million on smoking-cessation medications overall; 69.3% of that spending was used for nonnicotine smoking-cessation medications, which constituted only 31.3% of the total number of smoking-cessation medications. The average price of nonnicotine medications ($250.95) was almost 5 times the average price of nicotine replacement products ($50.70; Table 2).

The last 3 columns of Table 2 show the annual pharmacy price per prescription for nonnicotine products, nicotine replacement agents, and the 2 medication classes combined. The average pharmacy reimbursement per prescription for nonnicotine products cost the Medicaid program $102.63 in 1997 and rose to $250.95 in 2015. In addition, the average pharmacy reimbursement per prescription for nicotine replacement products rose from $59.46 in 1991 to $116.02 in 1997, and then fell to $50.70 in 2015.

Figure 1 (page 277) and **Figure 2** depict the quarterly trends of utilization for nonnicotine products and nicotine replacement medications by generic and brand manufacturers. The most striking trend in Figure 1 is the rising utilization of Chantix among Medicaid beneficiaries. The number of prescriptions for Chantix increased

Table 3 Average per-Prescription Prices for Smoking-Cessation Medications in 2015

Smoking-cessation product type	Generic name	Brand name	Average brand-name price, $	Average generic price, $
Nonnicotine medications	Varenicline	Chantix	251.31	NA
	Bupropion	Zyban	168.88	36.56
OTC nicotine replacement products	Nicotine	Habitrol	NA	43.80
		Nicoderm	66.59	
		Nicorette	81.13	
		Commit	NA	
Prescription-only nicotine replacement products		Nicotrol	277.45	
		Prostep	NA	

NA indicates not available; OTC, over-the-counter.

Figure 2 Quarterly Utilization of Nicotine Replacement Products for Patients with Medicaid Coverage, 1991 to Mid-2015

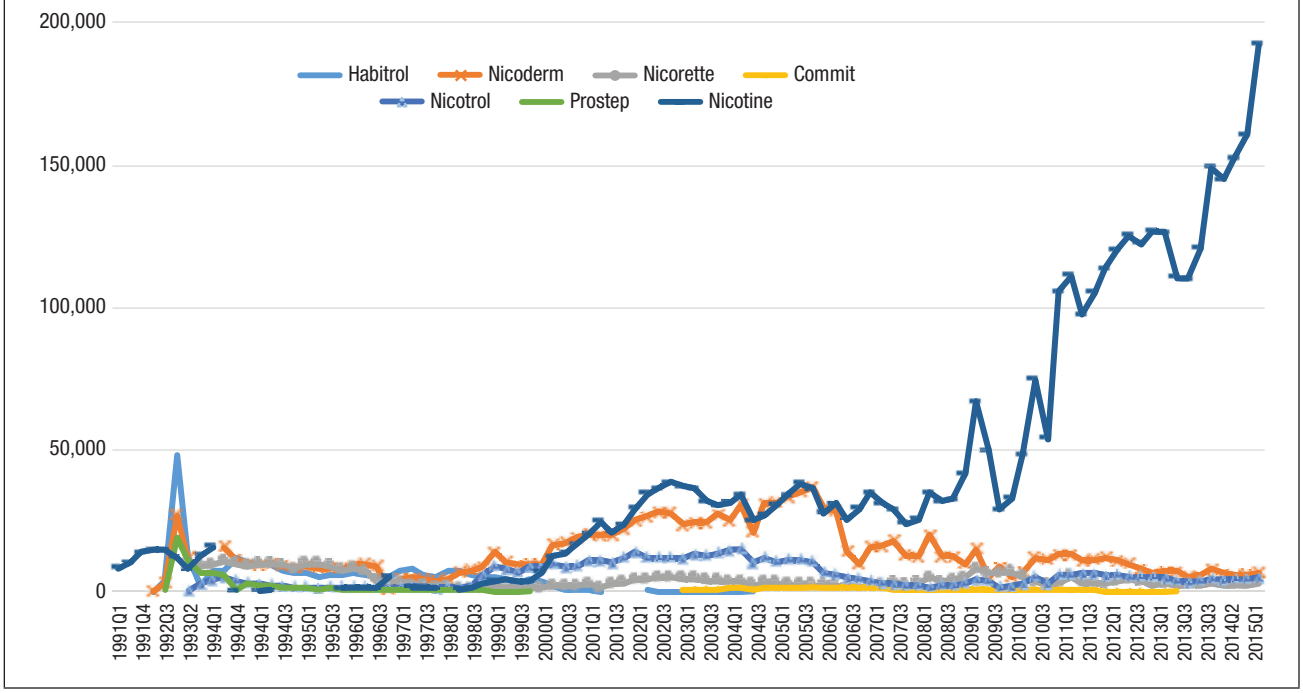
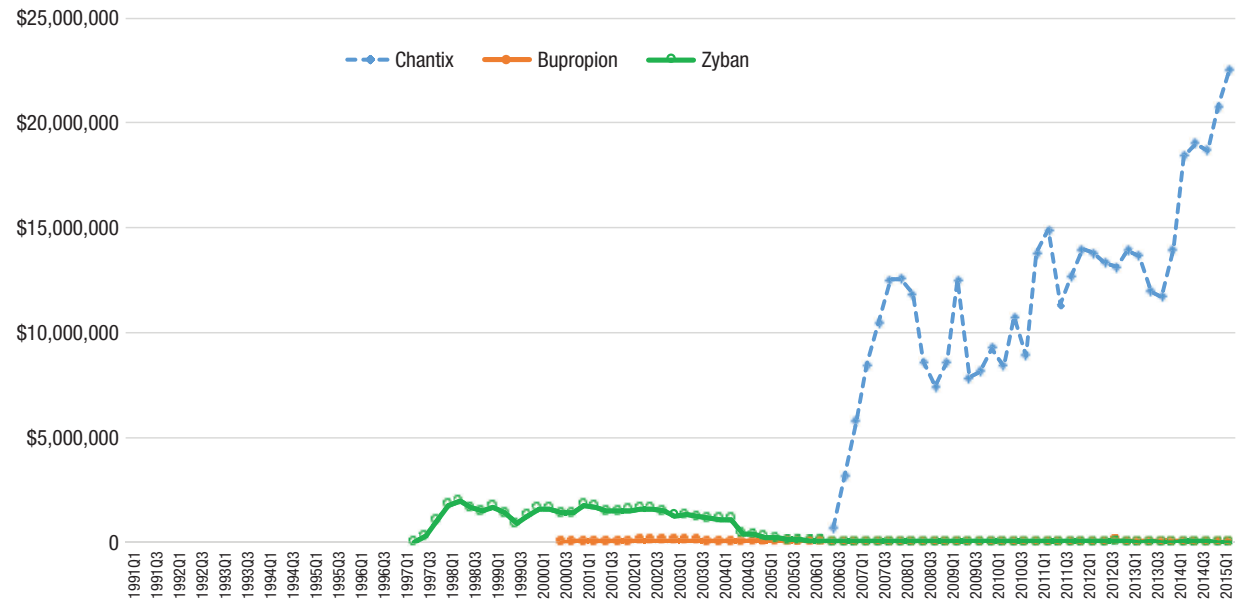


Figure 3 Quarterly Pharmacy Reimbursement for Nonnicotine Medications for Patients with Medicaid Coverage, 1991 to Mid-2015



NOTE: All reimbursement amounts above were inflated to 2015 US dollars using the medical services component of the Consumer Price Index.

13,277% from 6215 prescriptions in the third quarter of 2006 to 88,735 in the second quarter of 2015, whereas the number of prescriptions decreased for Zyban and generic bupropion in the same period.

As seen in Figure 2, generic nicotine clearly dominated the nicotine replacement market. The utilization of generic nicotine products skyrocketed during the last 5 years of the study. **Figure 3** and **Figure 4** show the quarterly trends of Medicaid reimbursement of individual nonnicotine products and nicotine replacement products.

Similar to the utilization trend, the Medicaid spending trend for smoking-cessation medications was dominated by Chantix and Nicotrol. There were 5 brand-name drugs with patents that expired during the study period (ie, Zyban, Nicotrol, Commit, Nicorette, and Habitrol). Because all state Medicaid programs either require or strongly encourage patients to use generic medications, there was an abrupt decrease in the utilization of brand-name medications, such as Zyban, Habitrol, Commit, and Nicotrol. The utilization and reimbursement of Zyban decreased as generic versions of drugs entered the market. (Because Habitrol, Nicotrol, and Commit had low utilization, it was difficult to display in Figure 2 and Figure 4.)

Finally, Prostep was ultimately withdrawn from the market because of severe adverse reactions; therefore, the utilization of Prostep was very limited during the time it was available.

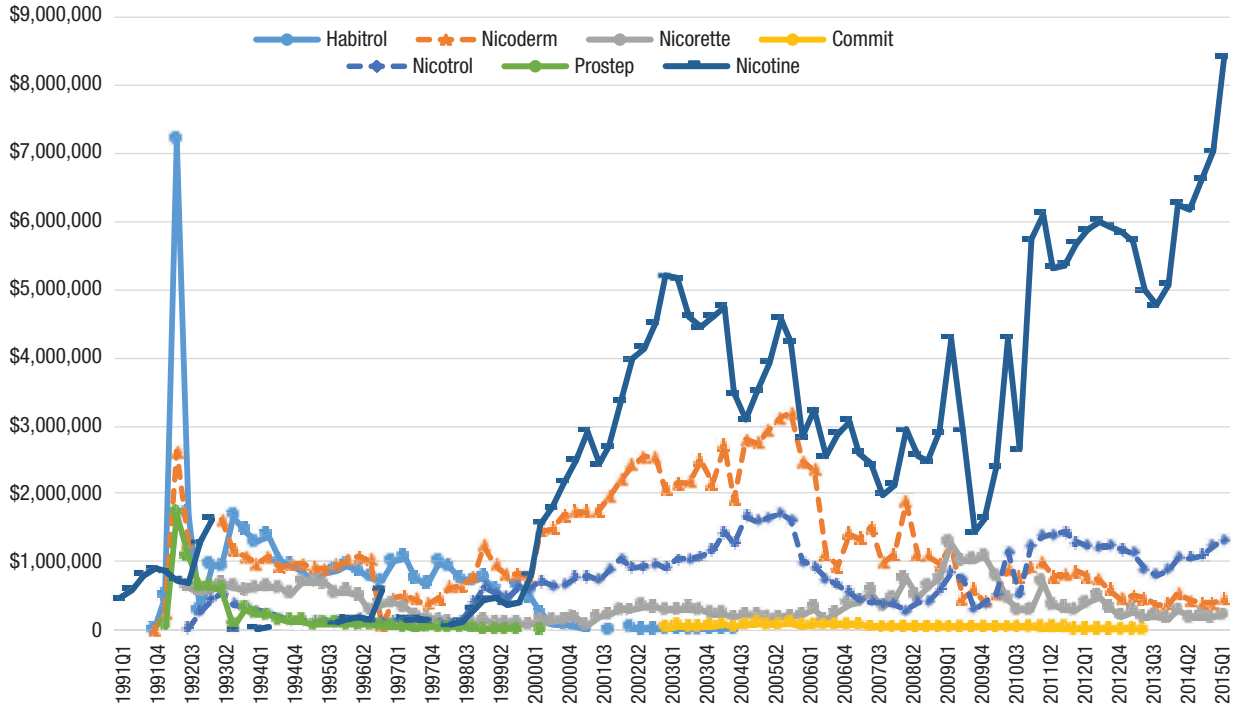
Table 3 shows the estimated drug prices of smoking-cessation medications, which were calculated by dividing Medicaid reimbursement dollars by the number of prescriptions in 2015. Trends in the average reimbursement per prescription for individual drugs are shown in **Figure 5** and **Figure 6**. Each of the smoking-cessation medications has a unique price trend. Although the price of Zyban slowly increased from 1997 to 2015, the price of Chantix climbed abruptly from $113.98 in quarter 3 of 2006 to $254.50 in quarter 2 of 2015.

Meanwhile, the price of bupropion slowly decreased from 1991 to 2010. Nicotine replacement products had large price changes as well. The price of Nicotrol continued to climb from $113.29 in quarter 3 of 1992 to $279.96 in quarter 2 of 2015. In addition, the price of Habitrol and Commit decreased, because generic manufacturers entered the market after the patent expiration date. As a result of the high price of brand-name nonnicotine medications per prescription, the total spending on nonnicotine agents in Medicaid was much more than nicotine replacement products.

Discussion

During the 25-year study period, a substantial rise in Medicaid expenditures on smoking-cessation medications was observed. The total number of Medicaid-reimbursed prescriptions for smoking-cessation medications increased rapidly from 46,396 in 1991 to 942,562 in

Figure 4 Quarterly Pharmacy Reimbursement for Nicotine Replacement Products for Patients with Medicaid Coverage, 1991 to Mid-2015



NOTE: All reimbursement amounts were inflated to 2015 US dollars using the medical services component of the Consumer Price Index.

2014, which is a more than 1931% increase. The rise in the number of prescriptions for these medications was much higher than the increase in the number of beneficiaries who enrolled in Medicaid over this same period. The average annual enrollment in Medicaid in 1990 was 22.9 million and increased to 68.9 million in 2015 (after the worst economic recession, between December 2007 and June 2009, in a quarter century), which is a 201% increase in the number of beneficiaries.

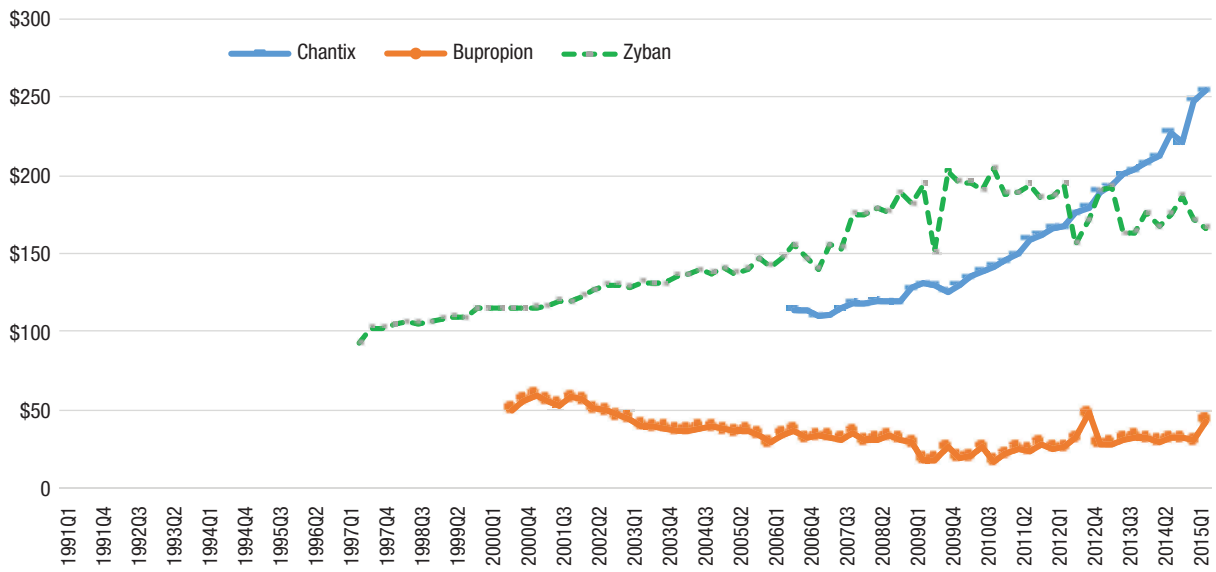
The trends seen in this study were similar to the trends seen in Medicaid spending, utilization, and prices for other drug classes studied previously, such as quinolones,[18] antiasthma,[19] antimigraine triptans,[20] antidepressants,[21] and antihypertensives.[22] According to our analysis, generic nicotine was the most frequently prescribed smoking-cessation medication for Medicaid beneficiaries. Varenicline also was often prescribed as a smoking-cessation medication for Medicaid beneficiaries; however, varenicline was not as popular as generic nicotine, because it was 6 times more expensive than generic nicotine.

Since Chantix came into the market in 2006, the dollar market share for nonnicotine drugs suddenly exceeded the dollar market share of nicotine replacement products and remained higher through 2015. Medicaid programs cannot take advantage of generic versions of these medications before the patent of the FDA-approved medication expires. Until then, Medicaid's expenditures on varenicline are expected to continue to increase for some years. The patent for Chantix will expire in May 2020.[23] Generic varenicline was tentatively approved by the FDA in December 2016, and we expect the reimbursement of Chantix to decrease after a generic version enters the market.

We found that once the patent protection expires on a brand-name drug, generic versions of the drug quickly become available. The market competition often leads to substantially lower prices, as was observed for Habitrol in the second quarter of 2004 and for Commit in the second quarter of 2013. By contrast, there was no impact on the expenditure for Medicaid for some brand-name drugs in the market after their patent expiration dates.

For example, Medicaid's expenditures of Zyban fell from $1.3 million to $3700 over the period from the first quarter of 2001 to the second quarter of 2015, but the average price per prescription of these medications rose over this period, because brand-name drug manufacturers raised drug prices to maximize revenue. In addition, some physicians and patients believe that the quality of brand-name drugs is better than that of generic drugs, so they keep using brand-name medications.

Figure 5 Average Reimbursement per Prescription for Nonnicotine Medications for Patients with Medicaid Coverage, 1991 to Mid-2015



NOTE: All prices were inflated to 2015 US dollars using the medical services component of the Consumer Price Index.

Limitations

The present study findings are limited by the available data extracted from the CMS national Medicaid pharmacy file. The OTC nicotine replacement therapy was available since 1996 and was covered by Medicaid since 2014[21,22]; however, state Medicaid programs did not cover the same nicotine replacement therapy products in all states. For example, the nasal spray, the inhaler, and the lozenge forms of nicotine replacement therapy are not all covered in Alaska, Arkansas, District of Columbia, Nebraska, South Dakota, and Texas.[22]

Although coverage for Zyban is available in each of the 50 states, it is not available in the District of Columbia.[22] We were unable to access specific percentage and utilization data on OTC or uncovered nicotine replacement therapy medications in different states. We observed some significant increases of nicotine replacement therapy utilization and expenditures after 2008, which may be a result of Medicaid expansion under the Affordable Care Act in some states[23]; however, we are unable to measure the specific impact of Medicaid expansion.

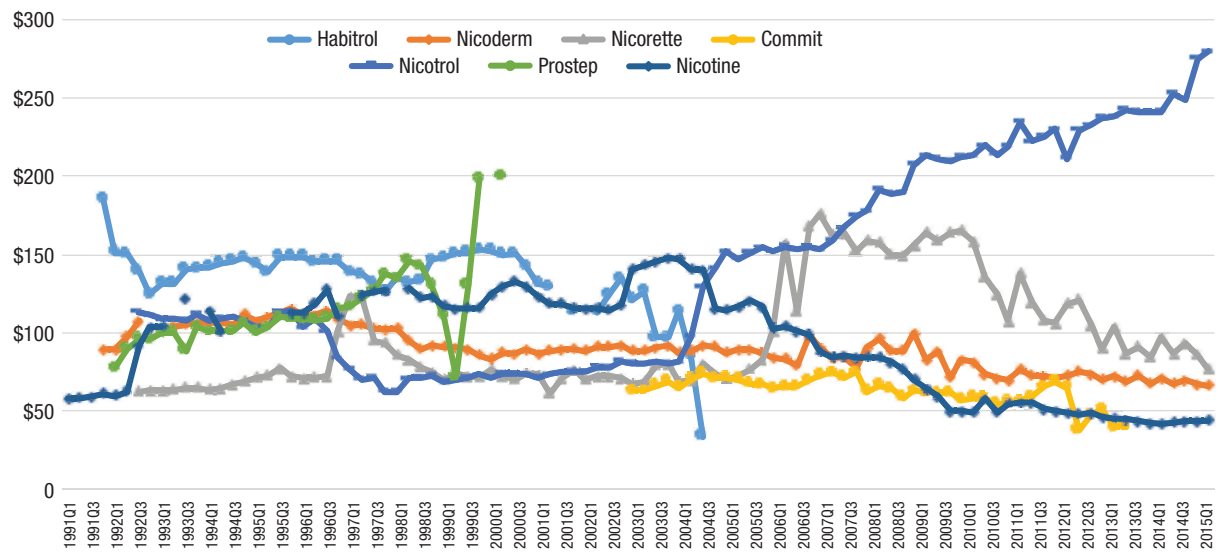
In addition, patient-specific information was not available in the national Medicaid database; hence, this study is a descriptive analysis, and other important patient-level information was not adjusted in a multivariate analysis. We cannot determine demographic characteristics and comorbidities, especially respiratory comorbidities, that may be correlated with the use of the different smoking-cessation aids. It was also not possible to determine the prescribed indication for medication use or whether the prescription was filled.

Furthermore, the provider level can influence the prescribing pattern of drugs. For example, certain providers may be more likely to prescribe one drug over another, which is a confounding factor that can result in a study bias. And no information is available about whether the utilization of smoking-cessation products among Medicaid beneficiaries has been appropriate, excessive, or insufficient. Thus, adherence to medication therapy could not be assessed.

Other misclassification biases may be present if the CMS data contained reporting errors. For 2006 (all quarters) and quarter 3 of 2007, some of the expenditure and utilization values had coding errors. To ensure data reliability, a few of the values in this study were imputed. Moreover, these data were from before the start of the Medicaid Drug Rebate Program. Therefore, they may overestimate the actual acquisition cost of US Medicaid programs.

Finally, the results of this study are specific to the Medicaid population, which is heavily comprised of low-income people, especially women and children. Thus, these data do not necessarily represent trends of utilization and expenditure in other populations that are covered by private health insurance or Medicare. Private health insurance companies may have covered more brand-name medications, which requires more investigation in future research. Also, sex and age distributions of

Figure 6 Average Reimbursement per Prescription for Nicotine Replacement Products for Patients with Medicaid Coverage, 1991 to Mid-2015



NOTE: All prices were inflated to 2015 US dollars using the medical services component of the Consumer Price Index.

Medicaid beneficiaries differ from those of the general US population.

Conclusion

Overall, by analysis of the Medicaid database, Medicaid expenditures and the number of prescriptions for smoking-cessation medications abruptly increased over the study period between 1991 and 2015. Our findings show that the market growth for varenicline far exceeded any other smoking-cessation products over the study years. The substantial increase in nonnicotine prescription and nicotine replacement therapy from 2007 to 2015 may be attributed to smoking-cessation participants nationwide. Cost-containment policies may have inadvertently prevented Medicaid smokers from obtaining the appropriate pharmacotherapy. ■

Author Disclosure Statement

Ms Yue and Dr Wigle have no conflicts of interest to report. Dr Guo has done research sponsored by Novartis, AstraZeneca, Bristol-Myers Squibb, Janssen Ortho-McNeil, Roche-Genentech, and Eli Lilly, none of which involved smoking-cessation medication.

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STAKEHOLDER PERSPECTIVE

The Importance and Benefits of Smoking-Cessation Therapy

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PATIENTS/PROVIDERS: More than a decade ago, Shiffman wrote about 3 process marker measures of success in smoking cessation, which include initially stopping smoking, avoiding a relapse to return to smoking, and if a relapse occurs, avoiding a return to continuous smoking after treatment tries and failures.[1] A 2011 study examined individual smoking-cessation therapies (ie, bupropion, nicotine lozenge, nicotine patch individual therapy) and combination (ie, bupropion plus lozenge, and patch plus lozenge) therapies.[2] This study's results indicated that all 5 therapies decreased the rates of failure to achieve initial smoking cessation and decreased relapse to smoking, with the exception of the nicotine lozenge; however, only the combination nicotine patch and bupropion affected the lapse to restarting smoking after abstinence.[2] These findings show that medications effectively help patients initially stop smoking and decrease the lapse risk, but that, in general, they do not decrease the risk for relapse after a lapse.[2] The effect of the prescription medication varenicline was not examined in this particular study.

In 2010, the Centers for Medicare & Medicaid Services (CMS) initiated a program using electronic health records (EHRs) to identify Medicaid- and Medicare-covered patients who smoked and who could receive a smoking-cessation treatment.[3] The meaningful use implementation of incentivizing providers to use EHRs to enhance smoking cessation was, and continues to be, successful. This EHR meaningful use of incentives increased the odds of successful patient cessation of smoking. Included in the sampling components were at-risk subpopulations of patients. Certain at-risk CMS insurance–covered subpopulations are at a significantly increased risk for morbidity and mortality because of smoking continuation. One such at-risk subpopulation is pregnant women who smoke, and therefore place themselves and their infants in a very high-risk situation that may lead to increased morbidity and mortality.[4]

In their impressive, extensive, complete, and methodologically sound meta-analysis of Medicaid smoking-cessation prices over 25 years, Yue and colleagues conclude that the enactment of cost-containment policies has had a negative impact on people obtaining proper therapies to assist in smoking cessation.[5] When barriers to obtaining smoking-cessation therapies based on the price of the products as the sole determining factor were eliminated, success was achieved in smoking-cessation efforts. Thus, comprehensive efforts that include cost-effectiveness and cost-utility analytic components are a much more realistic method of examining costs and outcomes of

STAKEHOLDER PERSPECTIVE *Continued*

therapeutic approaches to effective smoking-cessation program evaluation.

The European Study on Quantifying Utility of Investment in Protection from Tobacco (EQUIPT) public health research project was initiated as a response to the catastrophic economic, health, and societal consequences of tobacco use in the United Kingdom.[6] EQUIPT was a multicenter, interdisciplinary comparative effectiveness study. The result of the study was an adapted return-on-investment protocol to assess the many positive effects of tobacco-cessation programs in Europe. Because of the success of the model in England, the EQUIPT model has now been successfully applied to several European countries (ie, Germany, the Netherlands, Spain, and Hungary) with resultant positive impact on individual- and population-level efforts to initiate, evaluate, and enhance smoking-cessation programs.[7]

The provision of payment for smoking-cessation therapies is a prime example of how the evaluation of benefits and costs must include multidimensional components for individuals as well as for the greater good of society.

Geller and colleagues examined the influence of provider engagement and encouragement of smoking-cessation advice, coupled with the availability of nicotine replacement products on multiethnic patient smoking-cessation success in public housing sites in Boston, MA.[8] The study showed that multiethnic patients who had proper provider engagement, along with the removal of barriers to obtaining smoking-cessation therapies, increased the use of these therapies and had resultant positive results with smoking-cessation success.[8]

In a large-scale simulated study of the health benefits and cost-effectiveness of annual clinician-provided tobacco-cessation counseling for youth and adult populations, Maciosek and colleagues found that a clinician counseling of the benefits of smoking cessation would reduce the lifetime average prevalence of smoking in youths by 2 percentage points and in adults by 3.8 percentage points.[9] Reducing smoking by these amounts would save money on smoking-related morbidity and mortality.

Zhu and colleagues state that smoking prevalence among Medicaid populations is declining at a negligible rate.[10] It is alarming in economic and clinical terms that the prevalence of smoking remained high and relatively unchanged between 1997 and 2013. Zhu and colleagues point to the ever-increasing chronic diseases in Medicaid populations and the relative pause of success in tobacco cessation as alarming joint dependent factors.[10]

The cost of any therapy must be examined through the assessment of many factors that include the cost of therapies to treat diseases, as well as short- and long-term views and analyses of what is saved in economic, clinical, and quality-of-life values and enhancements. The provision of payment for smoking-cessation therapies is a prime example of how the evaluation of benefits and costs must include multidimensional components for individuals as well as for the greater good of society. ■

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